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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,994	02/27/2001	Edmonds Taylor Brian	X-12239	6826

7590

09/30/2003

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,994

Applicant(s)

BRIAN, EDMONDS TAYLOR

Examiner

DAVID ROMEO

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) **32-36 and 38**, drawn to an hLTBP-3 polypeptide and compositions comprising same, and a method of producing a polypeptide, a nucleic acid encoding the hLTMP-3 polypeptide comprising, vectors, and host cells comprising same.

Group 2, claim(s) **37 and 39**, drawn to an antibody and compositions comprising same.

Group 3, claim(s) **40 and 43**, drawn to a method for inhibiting or stimulating tissue growth which comprises administering to a patient in need thereof a *polypeptide*.

Group 4, claim(s) **41 and 42**, drawn to a method for inhibiting tissue growth which comprises administering to a patient in need thereof an *antibody*.

Group 5, claim(s) **44**, drawn to a method for modulating a TGF $\beta$  regulatable activity comprising administering an *antibody*.

Group 6, claim(s) **45**, drawn to a method for modulating a TGF $\beta$  regulatable activity comprising administering an *antisense nucleic acid*.

Group 7, claim(s) **46**, drawn to a method for prevention and/or treatment comprising administering a *polypeptide*.

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Group 8, claim(s) 47, drawn to a method for prevention and/or treatment comprising administering an *antibody*.

4. The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group 1 recites the special technical feature of a nucleic acid encoding a polypeptide, which is not required by any of the other Groups.

Group 2 recites the special technical feature of an antibody, which is not required by any of the other Groups.

Group 3 recites the special technical feature of stimulating tissue growth, which is not required by any of the other Groups.

Group 4 recites the special technical feature of inhibiting tissue growth by administering an antibody, which is not required by any of the other Groups.

Group 5 recites the special technical feature of modulating TGF $\beta$  regulatable using an antibody, which is not required by any of the other Groups.

Group 6 recites the special technical feature of an antisense nucleic acid, which is not required by any of the other Groups.

Group 7 recites the special technical feature of using a polypeptide as a therapeutic agent, which is not required by any of the other Groups.

Group 8 recites the special technical feature of using an antibody as a therapeutic agent, which is not required by any of the other Groups.

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5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

6. In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

- a. SEQ ID NO: 2
- b. SEQ ID NO: 4
- c. SEQ ID NO: 5
- d. SEQ ID NO: 6

7. **If applicant selects any one of Groups 1-8, one species from the SEQ ID NO must be chosen to be fully responsive.**

8. In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

- e. Cancer
- f. Fibrosis
- g. Osteoporosis
- h. Myocardial infarction
- i. Congestive heart failure
- j. Dilated cardiomyopathy
- k. Deep venous thrombosis
- l. Disseminated intravascular thrombosis
- m. Stroke

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- n. Sepsis
- o. Injuries involving major tissue damage and trauma
- p. Systemic inflammatory response syndrome
- q. Sepsis syndrome
- r. Septic shock
- s. Multiple organ dysfunction syndrome (including DIC)
- t. Atherosclerotic plaque rupture
- u. Associated sequela

**9. If applicant selects either Groups 7 or 8, one species from the disease group must be chosen to be fully responsive.**

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **David Romeo, Ph.D.** whose telephone number is 703-305-4050.

The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
September 29, 2003

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**